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In re Application of:

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Serial No.: **09/763,831**

Group Art Unit: **3745**

**TECHNOLOGY CENTER R3700**

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For: **OMEPRAZOLE FORMULATION**

New York, NY 10036  
March 24, 2003

Commissioner of Patents & Trademarks  
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**INFORMATION DISCLOSURE STATEMENT**

Sir:

The following statement of relevance is submitted with the accompanying Form PTO/SB/08A.

<u>Document Designation</u>	<u>Relevance</u>
AA U.S.P. 4,045,563	Relates to a substituted 2-[pyridylalkylenesulfinyl]-benzimidazoles with gastric acid secretion inhibiting effects.
AB U.S.P. 4,045,564	Relates to benzimidazole derivatives useful as gastric acid secretion inhibitors.
AC U.S.P. 4,182,766	Relates to naph[2,3-d]imidazoles.

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<u>Document Designation</u>	<u>Relevance</u>
AD U.S.P. 4,255,431	Relates to a gastric acid secretion inhibiting substituted 2-(2-benzimidazolyl)-pyridines, pharmaceutical preparations containing same, and method for inhibiting gastric acid secretion.
AE U.S.P. 4,337,257	Relates to gastric acid secretion inhibiting substituted 2-(2-benzimidazolyl)-pyridines, their preparations containing same, and method for inhibiting gastric acid secretion.
AF U.S.P. 4,359,465	Relates to methods for treating gastrointestinal inflammation.
AG U.S.P. 4,432,966	Relates to compressed tablets for disintegration in the colon comprising an active ingredient containing nucleus coated with a first layer containing microcrystalline cellulose which is coated with an enteric organic polymer coating.
AH U.S.P. 4,508,905	Relates to substituted 2-(benzimidazolyl) pyridines.
AI U.S.P. 4,544,750	Relates to certain pyridyl-N-oxide intermediates for the preparation of omeprazole.
AJ U.S.P. 4,620,008	Relates to processes for the preparation of omeprazole and intermediates therefore.
AK U.S.P. 4,636,499	Relates to sulphenamides.
AL U.S.P. 4,686,230	Relates to a picoline derivatives useful as gastric acid secretion inhibitors.
AM U.S.P. 4,738,974	Relates to base addition salts of omeprazole.
AN U.S.P. 4,786,505	Relates to a new pharmaceutical preparation for oral use containing omeprazole.
AO U.S.P. 4,840,799	Relates to a process for preparing rapidly disintegrating particles.
AP U.S.P. 4,853,230	Relates to pharmaceutical formulations of acid labile substances for oral use.
AQ U.S.P. 5,045,321	Relates to a stabilized pharmaceutical composition and its production.

AR U.S.P. 5,093,132	Relates to a stabilized pharmaceutical composition and its production.
AS U.S.P. 5,093,342	Relates to the use of omeprazole as an antimicrobial agent.
AT U.S.P. 5,178,867	Relates to a dosage form for delivering drug in short time period.
AU U.S.P. 5,204,118	Relates to pharmaceutical compositions and methods for treating the symptoms of indulgence.
AV U.S.P. 5,244,670	Relates to an ingestible pharmaceutical composition for treating upper gastrointestinal tract distress.
AW U.S.P. 5,288,506	Relates to antacid compositions with prolonged gastric residence time.
AX U.S.P. 5,304,540	Relates to pharmaceutical compositions and methods for using the same.
AY U.S.P. 5,330,982	Relates to a pharmaceutical composition containing a 5 HT receptor antagonist and a method of treating gastrointestinal disorders therewith.
AZ U.S.P. 5,352,688	Relates to a method for the treatment of bradyphrenia in Parkinson's disease.
BA U.S.P. 5,362,424	Relates to a microencapsulation for controlled oral drug delivery system.
BB U.S.P. 5,385,739	Relates to stable compositions of gastroprotected omeprazole microgranules and process for the production thereof.
BC U.S.P. 5,389,664	Relates to alleviating stomach ulcers in swine.
BD U.S.P. 5,399,700	Relates to method for preparing enteric coated oral drugs containing acid unstable compounds.
BE U.S.P. 5,417,980	Relates to pharmaceutical compositions and methods for treating the symptoms of overindulgence.
BF U.S.P. 5,433,959	Relates to a stabilized pharmaceutical composition.
BG U.S.P. 5,508,041	Relates to microencapsulation for controlled oral drug delivery system.

BH U.S.P. 5,518,730	Relates to a biodegradable controlled release flash flow melt spun delivery system.
BI U.S.P. 5,599,794	Relates to a synergistic combination of a substance with gastric acid secretion inhibiting effect and an acid degradable antibiotic.
BJ U.S.P. 5,620,964	Relates to compositions for treating and inhibiting gastric and duodenal ulcers.
BK U.S.P. 5,622,717	Relates to ulcer prevention using a melt spun hydrogel.
BL U.S.P. 5,637,320	Relates to a controlled absorption naproxen formulation for once-daily administration.
BM U.S.P. 5,639,478	Relates to a method to stabilize a pharmaceutical composition and its production.
BN U.S.P. 5,693,818	Relates to a process for preparing pure salts of pyridinylmethyl-sulfinyl-1h-benzimidazole.
BO U.S.P. 5,753,265	Relates to a multiple unit pharmaceutical preparation.
CA WO 85/03436	Relates to diffusion coated multiple units dosage form.
CB WO 95/01783	Relates to a new pharmaceutical formulation.
CC WO 95/10264	Relates to a tablet containing enteric granules.
CD WO 95/12590	Relates to a preparation of omeprazole and lansoprazole and intermediates useful therein.
CE WO 96/01612	Relates to a novel drug delivery system.
CF WO 96/01622	Relates to a new oral pharmaceutical formulation containing magnesium salt of omeprazole.
CG WO 96/01623	Relates to multiple unit tableted dosage form.
CH WO 96/24375	Relates to a new pharmaceutical dosage form.

CI WO 96/02535	Relates to a process for synthesis of substituted sulfoxides.
CJ CA 1,127,158	Relates to 2-pyridymethylsulfinyl-benzimidazole compounds.
CK CA 1,129,417	Relates to gastric acid secretion inhibiting substituted 2-(2-benzimidazolyl)-pyridines, their preparation, pharmaceutical preparations containing same, and method for inhibiting gastric acid secretion.
CL CA 1,234,118	Relates to pyridyl-n-oxide intermediates for the preparation of omeprazole.
CM CA 1,263,119	Relates to production of 2-(2 pyridylmethylsulfinyl) benzimidazole compounds.
CN CA 1,264,751	Relates to base addition salts of omeprazole.
CO CA 1,292,693	Relates to a pharmaceutical preparation containing omeprazole.
CP CA 1,302,891	Relates to pharmaceutical formulations of acid labile substances for oral use.
CQ CA 1,324,758	Relates to transdermal antisecretory agents for gastrointestinal disease.
CR CA 1,338,377	Relates to stabilized pharmaceutical composition and its production.
CS CA 2,037,101	Relates to omeprazole compositions designed for administration in rectum.
CT CA 2,046,364	Relates to galenic process for omeprazole containing pellets.
CU CA 2,083,605	Relates to method for synthesis.
CV CA 2,139,653	Relates to optically pure salts of pyrinylmethyl sulfinyl-1H-benzimidazole compounds.
CW CA 2,140,347	Relates to injection and injection kit containing omeprazole and its analogs.
CX CA 2,166,483	Relates to a new pharmaceutical formulation.

CY	Relates to magnesium omeprazole.
CA 2,166,794	
CZ	Relates to multiple unit tableted dosage form.
CA 2,170,647	
DA	Relates to a new oral pharmaceutical containing magnesium salt of omeprazole.
CA 2,193,681	
DB	Relates to pyridylalkyloxy and pyridyalkythioazole derivatives.
GB 1,234,058	
DC	Relates to omeprazole salts.
EPO 124,495	
EA	Relates to omeprazole.
L. Olbe, S.E. et al., Present Situation and Future Prospects of Medical Treatment., <u>Gastrins and the Vagus</u> , Academic Press p. 245-250, 1979.	
EB	Relates to omeprazole.
Ekenved et al. "Studies with H 168/68, a Novel Gastric Acid Secretion Inhibitor., <u>Gut</u> , Vol. 22, No. 10, October 1981 p. A877.	
EC	Relates to omeprazole.
Erik Fellenius et al., Substituted Benzimidazoles Inhibit Gastric Acid Secretion by Blocking (H <sup>+</sup> + K <sup>+</sup> ) ATPase., <u>Nature</u> , Vol. 290, March 12, 1981 p. 159-161	
ED	Relates to omeprazole.
Tore Lind, et al., Effect of Omeprazole – A Gastric Proton Pump Inhibitor on Pentagastrin Stimulated Acid Secretion in Man., <u>Gut</u> , Vol. 24 p. 270-276, 1983.	
EE	Relates to omeprazole.
K-Fr Sewin et al., Effect of Substituted Benzimidazoles on Acid Secretion in Isolated and Enriched Guinea Pig Parietal Cells., <u>Gut</u> , Vol. 24 p. 557-560, June 1983.	

**EE** Relates to omeprazole

Haken Larsson et al., Inhibition of Gastric Acid Secretion by Omeprazole in the Dog and the Rat. Gastroenterology, Vol. 85 p. 900-907, October 1983.

**EG** Relates to omeprazole.

Walter Londong et al. Dose-Response  
Study of Omeprazole on Meal-Stimulated  
Gastric Acid Secretion and Gastrin Release.,  
Gastroenterology, Vol. 85 p. 1373-1378,  
December 1983.

**EH** Relates to omeprazole.

Stanislaw J. et al., Effects of Omeprazole, a Substituted Benzimidazole, on Gastrointestinal Secretions, Serum Gastrin and Gastric Mucosal Blood Flow on Dogs. *Gastroenterology*, Vol. 86, p. 71-77, January 1984.

EI Relates to omeprazole.

D.A. Henry et al., Omeprazole:  
Effects on Oxidative Drug Metabolism.,  
British Journal of Clinical Pharmacology,  
Vol. 18, p. 195-200, August 1984.

EJ Relates to omeprazole.

B.K. Sharma et al., Optimal Dose of Oral Omeprazole for Maximal 24 Hour Decrease of Intragastric Acidity. Gut, Vol. 25 p. 957-964, September 1984.

**EK** Relates to omeprazole.

H.P.M. Festen et al., Effect of Oral Omeprazole on Serum Gastrin and Serum Pepsinogen I Levels. Gastroenterology, Vol 87 p. 1030-1034, November 1984.

**EL** Relates to omeprazole.

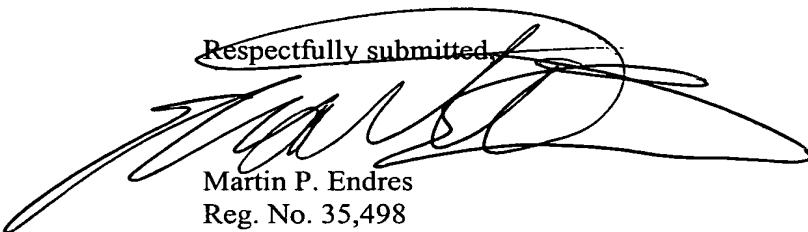
Peter Prichard et al. Omeprazole:  
A Study of Its Inhibition of Gastric pH  
and Oral Pharmacokinetics After  
Morning or Evening Dosages  
Gastroenterology, Vol. 88 pp. 64-69  
January 1985.

EM	Relates to omeprazole.
K.O. Borg and L. Olbe, Omeprazole – A Survey of Preclinical Data, <u>Gastroenterology</u> , p. 15-22, 37-51, 71-77, 79-93, 105-120, June 1985.	
EN	Relates to omeprazole.
50 <sup>th</sup> Edition of Physician's, 1996 Desk Reference p. 529—531.	
EO	Relates to omeprazole.
K.O. Borg, L. Olbe Proceedings of the First International Symposium on Omeprazole, Supplement to the <u>Scandinavian Journal of Gastroenterology</u> , pp. 11-17, 31-38, 54-56, 59-60, 75-76, 77-78, 89-91, 92-98, 99-104, 105-135, 179, 182-183, 187-195, 1996.	
FA	Relates to omeprazole formulations.
U.S.P. 6,096,340	
FB	Relates to a new pharmaceutical formulation and process.
WO 96/24338	
FC	Relates to an oral pharmaceutical preparation comprising an
EP 1010423 A2	antiulcer activity compound, and process for its production.
FD	Relates to omeprazole formulation.
September 23, 1994 Decision of the Korean Patent Office Regarding Korean Patent No. 55426 with Certified English Translation See page 4, line 13 to page 5, line 8.	
FE	Relates to omeprazole formulation.
Korean Patent Application 92-17571 with Certified English Translation	

Full text copies or abstracts of the above-identified reference were previously supplied in application Serial No. 09/143,167 with the exception of reference FA-FE. Pursuant to 37 C.F.R. 1.98 (d) copies of references AA-EO are not provided with this Information Disclosure Statement because copies of these references were supplied in the parent application, Serial No. 09/143,167. If additional copies are needed, the Examiner is invited to telephone the undersigned and copies will be immediately provided.

Copies of references FA-FE are enclosed. It is respectfully requested that this art be considered by the Examiner in the above-entitled application and made or record therein. Because the first and non-final Office Action has been issued in this matter, a check in the amount of \$180.00 is enclosed pursuant to 37 C.F.R. §1.97(c)(2). If any additional fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 08-1540.

Respectfully submitted,



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